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WHAT IS THE FDA DOING TO REDUCE THE DIABETES AND OBESITY EPIDEMICS IN AMERICA AND TAKE ON THE GREED OF THE FOOD AND BEVERAGE INDUSTRY?

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED EIGHTEENTH CONGRESS

SECOND SESSION

ON

EXAMINING WHAT THE FOOD AND DRUG ADMINISTRATION IS DOING TO REDUCE THE DIABETES AND OBESITY EPIDEMICS IN AMERICA, FOCUSING ON THE FOOD AND BEVERAGE INDUSTRY

DECEMBER 5, 2024

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C O N T E N T S

STATEMENTS

THURSDAY, DECEMBER 5, 2024

WHAT IS THE FDA DOING TO REDUCE THE DIABETES AND OBESITY EPIDEMICS IN AMERICA AND TAKE ON THE GREED OF THE FOOD AND BEVERAGE INDUSTRY?

Thursday, December 5, 2024

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The Committee met, pursuant to notice, at 10:02 a.m., in room 562, Dirksen Senate Office Building, Hon. Bernard Sanders, Chairman of the Committee, presiding.

Present: Senators Sanders [presiding], Casey, Baldwin, Kaine, Hassan, Smith, Hickenlooper, Markey, Cassidy, Murkowski, Braun, Marshall, Tuberville, and Budd.

OPENING STATEMENT OF SENATOR SANDERS

The CHAIR. The Senate Committee on Health, Education, Labor, and Pensions will come to order. If there is a mantra that exists in this Committee, I think on both sides of the aisle, it is that an ounce of prevention is worth more than a pound of cure. And that is going to be what we'll be discussing today.

In America, it is no secret to anybody that we have a major obesity epidemic as well as an epidemic in diabetes. They are both directly related and they are both getting worse. More than 35 million Americans have type 2 diabetes. Over 10 percent of our population. 10 percent of our population, and about 90 percent of those with type 2 diabetes are obese. Diabetes is not only a serious illness unto itself, but it is a contributing factor to heart disease, stroke, amputations, blindness, and kidney failure, and the cost of treating these illnesses is staggering.

According to the American Diabetes Association, the total cost of diabetes in the United States was nearly $413 billion. $413 billion, up 27 percent over the past 6 years. This amounts to about 10 percent of our total healthcare expenditures. That is an unbelievable and unsustainable amount of money.

When we talk about the type 2 diabetes epidemic and the huge increase in new cases, we must also talk about the epidemic of obesity in our Country. Some 90 percent of people with type 2 diabetes are overweight or obese. These two epidemics go hand in hand. The time is long overdue for us to pose some very simple questions, and that is what this hearing is about today.

How did it happen that according to the CDC, the rate of childhood obesity in America has tripled since the 1970's, and has gotten so bad that one out of every five children in our Country is now obese. How has it happened that over 40 percent of adults in the United States today are obese? And in my view, the answers to these questions are not very complicated.

For decades, Congress and the FDA have allowed large corporations to make huge profits by enticing children and adults to consume ultra-processed food and beverages loaded up with sugar, salt, and saturated fat. There is growing evidence, including testimony that we have heard right here in this Committee, that these foods are deliberately designed to be addictive, similar to cigarettes and alcohol, and lead to a higher rate of type 2 diabetes.

Shockingly, according to a study published in the British Medical Journal, ultra-processed foods make up an incredible 73 percent of our Nation's food supply. Bottom line. Much of the food that we as Americans are now consuming are making us unhealthy and are contributing to the fact that our life expectancy is significantly lower than that of many other wealthy countries.

None of this is happening by accident. The food and beverage industry is spending $14 billion a year on advertising to push these unhealthy products onto the American consumer. Even worse and really unacceptable, $2 billion of this money is spent to directly advertise these unhealthy products to our children in order to get them hooked on these foods at an early age.

According to the Rudd Center for Food Policy and Obesity, children and teens view about 4,000 food and beverage ads on television each year, an average of 10 advertisements per day. Last year, for example, Coca-Cola spent $327 million on advertising in the United States alone, while it raked in more than $9.5 billion in profits.

Not one of these ads will tell you that a 20-ounce bottle of Coke contains more than 15 teaspoons of sugar, 15 teaspoons of sugar over twice the recommended daily limit for kids. Not one of these ads will tell you that drinking one can of Coke a day could increase your chance of getting type 2 diabetes by up to 26 percent.

Given this reality, which has been widely discussed by scientists and doctors for decades, this really is not new news. The question then arises; what has the Food and Drug Administration, the FDA, done to address these epidemics, which have impacted the health of millions of Americans and cost us hundreds of billions of dollars each year? As far as I can tell, the answer is not much.

Way back in 2010, the National Academy of Medicine recommended that the food and beverage industry be required to put nutrition labels on the front of their products that the American people could easily understand. That was in 2010. On June 13th, 2023, the FDA announced that it would propose a rule to require the food and beverage industry to put nutrition labels on the front of their products no later than October 2023. The FDA missed that deadline.

On December 6th, 2023, FDA announced that this proposed rule would be made public in June 2024. The FDA missed that dead-

line. On July 5th, 2024, the FDA announced that this proposed rule will be made public by October 2024. The FDA missed that deadline. I have been told that on November 21st, 2024, after more than 14 years of inaction, the FDA finally sent this proposed rule to the Office of Management and Budget for their review, but has still not been made public. That is unacceptable.

In 2016, Chile implemented a law mandating warning labels on the front of unhealthy food and beverage products. After this law was implemented, calories consumed from these products went down by 24 percent. Similar labels were put into effect in Peru in 2019, and Israel, and Mexico, in 2020, in Uruguay in 2021. And in Brazil, Columbia, Argentina, and Venezuela, from 2022 to 2024.

Nearly 30 years ago, the FDA and Congress had the courage to take on a tobacco industry whose products killed over 400,000 Americans every year, including my father. And as a result of these actions, smoking rates among adults dropped from 43 percent in 1965 to 12 percent in 2023. Smoking rates among teens dropped even more significantly. That effort was a major success.

Now is the time for us to seriously combat the type 2 diabetes and obesity epidemics in this country. In order to do that, we must have the courage to take on the greed of the food and beverage industry, which every day is undermining the health and well-being of our children.

For starters, we need strong front-of-package food labels so that all consumers, especially children, can be warned as to which products are harmful to their health. Tobacco labels in the United States do not say, "High in tar," or, "High in nicotine," "High in carcinogens." They say, "Cigarettes cause lung cancer, emphysema, and may complicate pregnancy."

Let's be clear, not only must we put strong warning labels on unhealthy food and beverages, we must also ban junk food ads targeted to children. The National Institute of Health has estimated that if the United States banned fast food advertising marketed to children, we could cut the childhood obesity rate by 18 percent. This is not a radical idea.

In the 1980's, Quebec banned junk food advertising to children under 13. Last summer, the World Health Organization called for countries to substantially reduce the marketing of junk food to children. And Norway, announced that it would be banning all food and beverage advertisements to kids. Ireland, Portugal, South Korea, Spain, Taiwan, and several other major countries have either seriously restricted or banned junk food ads targeted to children. Not a radical idea.

Finally, in my view, we have got to substantially—and this Committee has dealt with this a whole lot—reduce the outrageously high prices of diabetes and weight loss drugs for Ozempic and Wegovy.

In April, I introduced legislation to enact a Federal ban on junk food advertising targeted toward children, and to require the FDA to put strong warning labels on products high in added sugar, salt, and saturated fat. So, today is an important hearing. We're dealing with the health and well-being of many millions of our people.

We're dealing with the need to substantially cut back on the hundreds of billions of dollars we now spend on diabetes.

We thank Dr. Califf and Mr. Jones for being with us.

Senator Cassidy, the mic is yours.

OPENING STATEMENT OF SENATOR CASSIDY

Senator CASSIDY. Thank you, Chair Sanders. Near 1 in 3 Americans live with obesity, including 14 million children. Nearly 1 in 10 have type 2 diabetes, one of many chronic diseases obesity is associated with, and obesity costs lives and results in $173 billion in healthcare spending per year.

When Obamacare was passed, there was a McKinsey report that said that unless we address the burden of chronic disease, we'll never control healthcare costs. And obesity is one of those things that was listed as those drivers of chronic disease. All this says that we must have solutions for both obesity and for the complications of which we have spoken. A great place to start is our Nation's food supply and the changes in Americans' diet over decades. According to analysis on internal medicine, 37 percent of adults consume an unhealthy diet.

Now, I'm pleased to say that reducing obesity, particularly among children is bipartisan. The incoming Trump administration is indicating that combating obesity, promoting healthy foods is a top priority. Many of President Trump's concerns around food transparency are echoed by Democratic colleagues, including Chair Sanders in the new majority. I am excited to work with President Trump and colleagues on this dais to examine these issues, crafting policies to enhance the health of Americans.

Today, we'll hear about the FDA's desire to implement a mandatory front-of-package label. Now, it's out of ordinary that we are holding a hearing before FDA has even released a formal proposal, but it's an important conversation. We must recognize, however, that food labeling reforms are not the end-all be-all, which is to say they are not a silver bullet in solving the Nation's health and obesity issues.

The Committee needs to look at all factors leading to obesity and how Congress can use its resources to promote a healthier lifestyle. This means examining FDA's role in reviewing the safety of chemicals and ingredients that go into our foods. It's important that FDA take a close look at existing review frameworks so foods are safe to consume. We also need to examine how Congress can better support robust scientific research on food ingredients, and I look forward to discussing this with FDA leadership.

I also want to hear from FDA about the progress that has been made in improving food safety duties under the Biden/Harris administration, FDA faced enormous challenges in regulating food safety, including the 2022 infant formula shortage, which severely impacted American families. These challenges led FDA to complete the largest reorganization in its history, and it's important that Congress provide oversight.

Beyond FDA, we know that the National Institutes of Health, NIH, habitually underfunds nutrition and obesity research, despite

its overwhelming impact on the health of our Country and impact on related medical conditions. Should there be more NIH funding looking at genetic predisposition? I think so. This is something I'll examine as Chair of HELP Committee in collaboration with the Trump administration.

I thank our witnesses for being here. I look forward to a productive discussion on how we can make America healthy again.

The CHAIR. Thank you, Senator Cassidy. Our witnesses today are Dr. Califf and Mr. Jones. Dr. Califf is the Commissioner of the U.S. Food and Drug Administration. He served previously in the Obama administration, as well as right now in the Biden administration.

Dr. Califf, thank you very much for being with us.

STATEMENT OF ROBERT CALIFF, M.D., COMMISSIONER, UNITED STATES FOOD AND DRUG ADMINISTRATION, SILVER SPRING, MD

Dr. CALIFF. Chair Sanders, and Ranking Member Cassidy, and Members of the Committee, thanks for the opportunity to testify, to discuss the Agency's efforts to reduce the chronic disease burden in America, and the role of our nutrition initiatives such as the proposed front-of-package labeling rule contribute to these efforts.

I've had the great honor to serve as the commissioner of the FDA, not once, but twice. I came back to FDA because I believe strongly in its mission and workforce. Americans have entrusted us with regulating industries that bear the responsibility of producing and distributing products that are safe and improve health.

While all the work FDA does is crucial, the greatest public health advancements we can make would be to improve the diet of Americans and eliminate the use of tobacco. The food we eat is contributing to America's unfortunate position with the lowest life expectancy among large high-income countries. I want to stress this; last place among large high-income countries in life expectancy.

Nearly everyone knows and cares for someone with a chronic disease. 6 in 10 Americans have at least one chronic disease, and 4 in 10 have two or more chronic diseases. I am deeply aware of this because my 35-year clinical career has been spent in direct care of suffering people with cardiovascular disease.

We all know that eating a nutritious balanced diet is a challenge for many people. Products that may appear nutritious could be loaded with sodium. People can exceed the recommended daily limit for added sugars with a single 16-ounce bottle of soda, and over 70 percent of our food supplies considered ultra-processed. As a recent Wall Street Journal editorial put it, "Americans eat unhealthy food because the food system is designed to feed it to them."

Meaningful change can only happen with serious action by Congress, the industry, and multiple state and Federal agencies. And of course, we're here today because this includes a major role in accountability of the FDA. FDA is trying to do its part within its authorities and budget, but successful change in the trajectory of our health depends on reaching a societal consensus that we will do this together.

When we pull the levers at our disposal, specific actions by FDA can have sweeping effects. When we required trans fat to be labeled on the Nutrition Facts label in 2006, we saw a nearly 80 percent drop in consumption because consumers picked different foods and industry reformulated their products.

Establishing a front-of-pack label could be another landmark policy. Displaying certain nutrition information right on the front of the package would allow Americans to quickly and easily identify how foods can fit into a healthy dietary pattern.

The health impact of ultra-processed foods is at the forefront of current policy considerations, and the clear association between ultra-processed food and negative health outcomes is a major concern. While there are still much we need to understand, ultra-processed foods are usually high in saturated fat, sodium, and added sugars, and there's already substantial evidence of harm when these nutrients are consumed in excess.

We are not waiting to act where the evidence is clear. In addition to front-of-pack nutrition labeling, FDA is working to reduce sodium across the food supply, update the "healthy" claim on food packages, and strengthen our chemical safety review program.

There is good reason to be concerned about the chemicals that are routinely included in much of our food. The FDA has limited resources to deal with this issue despite repeated requests for funding for much needed additional experts to do the evaluations. There are years of work under each of these initiatives that are performed by highly qualified and dedicated staff in the face of multiple limitations in the existing science, extensive legal hurdles, and direct opposition from powerful industry forces.

We have just completed the largest reorganization in FDA's history, in no small part, so that we could take on the issues of nutrition and chemicals in our food supply. As you know, I'll be leaving FDA at the change of administrations, but I can assure you that our people at FDA want to do more and we need your partnership.

As a cardiologist, I've spent most of my career dealing with the tragedy of premature death and disability. But my time in Washington has made me aware of how hard it is to address these policy issues. Our Nation's complex financial and industrial interest, combined with our national instinct to favor individual freedom to choose even if the choice is one that impairs health, make it difficult to take actions that have been successfully deployed by many other countries.

I believe these differences directly lead to better health and longer life in every other large high-income country compared with ours. In my opinion, finding a better consensus on these issues in America is not just an opportunity, but a necessity for the future of our Country.

Thanks for the opportunity to testify today, and we'll be happy to answer your questions.

[The prepared statement of Dr. Califf follows.]

PREPARED STATEMENT OF ROBERT CALIFF AND JIM JONES

Introduction

Chair Sanders, Ranking Member Cassidy, and Members of the Committee, thank you for the opportunity to testify before you today to discuss efforts to reduce the chronic disease burden in America and the Food and Drug Administration's (FDA or the Agency) front-of-package nutrition labeling initiative.

This is an important time to testify before this Committee on a growing and vitally urgent issue facing Americans: chronic disease, including diet-related chronic disease. The food we eat is exacerbating America's tragic title for the lowest life expectancy among large high-income countries. [1]

Chronic diseases, including heart disease, cancer, and diabetes, are the leading cause of disability and death in America. They are also the leading drivers of the Nation's $4.5 trillion in annual health care costs. Nearly everyone knows and cares for someone with a chronic disease: 6 in 10 Americans have at least one chronic disease and 4 in 10 have two or more chronic diseases. [2] Unfortunately, the toll of diet-related chronic diseases is even greater for racial and ethnic minority groups, those with lower socioeconomic status, and those living in rural areas. The burden of diet-related chronic diseases translates into astronomical health care and economic costs as well.

While there are myriad factors influencing health, the science is well settled to support that poor nutrition—including insufficient consumption of fruits, vegetables, and whole grains, as well as excessive consumption of saturated fat, sodium, and added sugars—increases the risk of diet-related diseases. Improving what we eat can be an effective remedy for diet-related disease, but changing diets is hard when challenged by externalities like finances, access to healthy food, education, health care, safe housing, job opportunities, neighborhood design, and transportation. Consequently, improving the American diet to help ensure food is a vehicle for wellness requires a whole-of-government and whole of society effort, including serious action from industry to be part of the solution.

Ultra-Processed Foods and Poor Health Outcomes

The health impact of ultra-processed foods (UPF) is at the forefront of many current discussions about nutrition. FDA agrees that the clear association between UPF and poor health outcomes is cause for major concern. Foods deemed ultra-processed are usually characterized by industrial processing, the presence of additives such as flavors or colors, and nutrients intended to make them appetizing (saturated fat, sodium, and added sugars).

There is still a lot we need to learn about UPF. For example, nutritious foods such as whole grain bread may be considered ultra-processed but are not necessarily associated with negative health outcomes and indeed have shown to be beneficial. [3] Yogurt and tofu are other examples. Additionally, infant formula and some medically necessary foods would also be considered UPF under some definitions, but are absolutely essential, nutritious foods. It is important that we better understand why and how UPF may be negatively impacting health to help inform targeted policies and avoid overly broad and impractical messages for consumers.

Still, we are not waiting idly for these answers. Later this month, FDA is convening a workshop with the National Institutes of Health (NIH) and a principal focus is to identify key priorities and critical next steps for research on UPF to help accelerate higher quality research. We are also aggressively taking policy steps where the evidence is clear.

A common characteristic of UPF is containing high levels of saturated fat, sodium, and added sugars. There is already substantial evidence of harm when these nutrients are overconsumed. In fact, much of the potential harm of UPF could be offset by taking actions that affect these nutrients. [4] FDA's efforts to better inform consumers through work on front-of-package nutrition labeling as well as on updating the claim "healthy," and our efforts to reduce sodium across the food supply, and strengthen our chemical safety review program, may help.

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[1] "How does U.S. life expectancy compare to other countries?" Peterson-KFF Health System Tracker, *https://www.healthsystemtracker.org/chart-collection/u-s-life-expectancy-compare-countries/*.

[2] *https://www.cdc.gov/chronic-disease/about/index.html*.

[3] *https://pubmed.ncbi.nlm.nih.gov/38417577/*.

[4] *https://www.sciencedirect.com/science/article/pii/S2667193X24000401*.

FDA's New Nutrition Center of Excellence—*Advancing Food as a Vehicle for Wellness*

FDA is well equipped to help lead the charge in improving nutrition in the U.S. On October 1, FDA undertook the largest reorganization in the Agency's recent history to establish the new, unified Human Foods Program (HFP), which included standing up a Nutrition Center of Excellence (NCE). Helping to ensure food is a vehicle for wellness is the vision of FDA's HFP, led by Jim Jones, FDA's first Deputy Commissioner for Human Foods.

The NCE elevates and empowers FDA's action on nutrition science, policy, and initiatives to play a central role in a broader, whole-of-government approach to reduce the burden of diet-related chronic diseases, improve health equity, and ensure the nutritional adequacy and safety of infant formula and other critical foods. A key characteristic of the NCE is expanding collaborations—inside and outside the Federal Government—to help achieve shared goals. The NCE also focuses strategic leadership and coordination of FDA's nutrition work and is prioritizing the Agency's ongoing efforts to encourage industry to offer more nutritious foods and help U.S. consumers make more informed food choices.

FDA's nutrition work provides significant dividends: for every dollar we invest in nutrition, we see a return of $119 in nutrition-related health benefits.[5] Even relatively modest investments can still have broad public health impact. We are eager to grow and strengthen the NCE to more adequately address diet-related disease and health equity and give these issues the attention they deserve.

Front-of-Package Nutrition Labeling and Additional Actions to Advance Public Health

Empowering Consumers through Front-of-Package Nutrition Labeling

Front-of-package (FOP) nutrition labeling is one avenue that could quickly and easily inform U.S. consumers about the levels of certain nutrients in foods, such as saturated fat, sodium, and added sugars which can increase the risk of diet-related diseases when consumed in excess and are commonly found at high levels in UPF. It could complement the Nutrition Facts label by displaying certain nutrition information right on the front of the food package, so it is immediately visible at the point of decision-making. It also has the potential to be as iconic as the Nutrition Facts label. For these reasons, publishing a proposed rule on FOP nutrition labeling is a priority for FDA.

There is tremendous value in getting the FOP nutrition labeling regulation right the first time. So, our effort to develop an FOP nutrition label has been vigorous and deliberative. FDA has done extensive research, analysis, and drafting, using all available tools and resources, to support a proposed FOP nutrition labeling rule so that it can benefit consumers.

As part of this effort, FDA built the scientific basis to inform our development of a proposed regulation to require an FOP nutrition label. We updated our thorough review of the scientific literature published in recent years by researchers in the United States and around the globe, foreign health agencies, and governmental bodies (such as the National Academy of Medicine). The literature review highlights that FOP labels have been widely found to be a useful tool in helping consumers identify and select healthy foods. With those research findings in hand, we then prepared our own research agenda.

We conducted two rounds of focus groups with U.S. adult food shoppers and conducted an experimental research study with over 9,000 consumers from diverse populations to ensure that everyone, including those most at risk for diet-related diseases, was adequately represented. The FOP schemes we tested align with insights from our focus group testing, review of the scientific literature, review of schemes from other countries, and with our legal authority. Findings from the scientific literature and the consumer research FDA conducted indicate that:

- FOP labels can help consumers identify healthy foods;
- Consumers prefer simple, interpretive FOP labels;
- FOP labels appear helpful for those with lower nutrition knowledge; and
- FOP labels complement the Nutrition Facts label.

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[5] https://reaganudall.org/operational-evaluation-fdas-human-foods-programs.

Alongside our research efforts, we undertook extensive outreach to facilitate an open and transparent process, so all interested parties had the opportunity to share their views. During this process we heard from consumer and public health groups, academia, health care groups, community members, as well as food companies and food trade associations. This included numerous individual meetings, four roundtable listening sessions, coalition meetings, and a public meeting on FOP Nutrition Labeling hosted by the Reagan-Udall Foundation for the FDA.[6]

The goal of these engagements was to hear interested parties' points of view and learn from their experiences with FOP nutrition labeling. While we are limited in the extent of information we can share with interested parties when developing a rule, we continue to share information as we are able, and we have an FOP webpage that is routinely updated. For example, our literature review and detailed information about our consumer research is available on the webpage.[7] We have also discussed our plans to develop a FOP nutrition label with our federal partners and had numerous discussions with foreign health officials in countries that have adopted FOP nutrition labeling to learn more about how their labels were designed, implemented, and evaluated.

Finally, we carried out the many steps to develop regulations, including an economic analysis, peer review of the data, and a legal analysis. We look forward to being able to discuss the details of our research and our proposal with the Committee and the public soon. We are confident it will reflect the research and what we have learned from consumers, academics, health advocates, and the food industry, as well as many others.

Providing a Refreshed Tool for Consumers by Updating the "Healthy" Claim

FOP nutrition labeling is one part of a suite of nutrition initiatives FDA is prioritizing. FDA also is working to finalize updates to the definition of the "healthy" nutrient content claim to reflect current nutrition science in the very near future. Voluntary claims like "healthy" on food labels can convey information to shoppers at a quick glance and help consumers identify foods that are the foundation of a healthy dietary pattern. FDA is also developing a "healthy" symbol that would be a graphic representation of the claim and is engaging with interested parties to find ways to support use of the claim and future symbol.

Fostering a Healthier Food Supply by Lowering Sodium

FDA continues to make great strides to help reduce sodium across the food supply, which has the potential to be one of the most important public health initiatives in a generation. In 2021, we issued Phase I voluntary sodium reduction targets, and we are seeing promising progress toward those targets.[8] We are very encouraged that our initial assessment of the Phase I targets showed that, in 2022, 40 percent of the Phase I targets had already been reached or were within 10 percent of meeting the targets. Additionally, recently released National Health and Nutrition Examination Survey (NHANES) 2021–2023 data show sodium intake levels at 3,113 milligrams (mg) per day, down from over 3,300 mg/day prior to 2021. This appears to be one of the largest decreases in decades and aligns with the trends we saw in our preliminary assessment—a very positive signal for the Agency's investment in sodium reduction efforts.

In August 2024, we started the next phase by issuing draft Phase II voluntary sodium reduction targets.[9] Together, the Phase I and Phase II targets would support reducing average sodium intake by about 20 percent from previous levels. FDA is receiving public comments on the draft Phase II targets and looks forward to finalizing them.

Together, FOP nutrition labeling, the "healthy" claim and symbol, and helping to reduce sodium in foods work cohesively as part of a government-wide approach to better inform consumers, improve nutrition, and reduce diet-related chronic diseases. These efforts can also help consumers more easily identify foods recommended by the Dietary Guidelines for Americans and may assist them in reduc-

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[6] *https://reaganudall.org/news-and-events/events/front-package-labeling*.

[7] *https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods/front-package-nutrition-labeling*.

[8] *https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods/sodium-reduction-food-supply#progress*.

[9] *https://www.fda.gov/food/food-labeling-nutrition/sodium-reduction-food-supply*.

ing consumption of certain nutrients that can be found in foods that are commonly considered ultra-processed.

Ensuring Food Chemical Safety and Protecting Human Health

FDA recognizes that there is also significant attention and concern around the presence of certain additives, such as flavors or colors, that are another common characteristic of UPF. During our public meeting in September on the Development of an Enhanced Systematic Process for FDA's Post-Market Assessment of Chemicals in Food,[10] FDA heard from a wide range of interested parties regarding UPF, the chemicals they contain, and the potential role these chemicals may play in chronic disease. Congress, state legislatures, and others have made clear that food chemical safety is a priority we need to address. We agree, and we are committed to leading the way on food chemical safety.

Under the new HFP, we are leveraging our scientific expertise and developing a more nimble and systematic approach to evaluating chemicals in the food supply. In particular, the Agency now has an office specifically dedicated to post-market assessments and is developing a process for conducting post-market assessments of chemicals previously evaluated for use in foods, which was discussed at the public meeting in September. FDA uses toxicity and biological data, along with data to estimate exposure, to support regulatory decisions allowing or restricting uses of substances according to our safety standard of reasonable certainty of no harm. This general approach assures there is an adequate margin between doses that can cause adverse effects and the exposure level in food.

FDA recognizes that there is a clear nexus between our nutrition goals and chemical safety goals. And we will act when data demonstrates a chemical in food causes harm. As an example, in 2015 FDA revoked the "generally recognized as safe" status of partially hydrogenated oils (PHOs) because various studies consistently linked PHOs consumption with heart disease. However, to date, the literature connecting UPF-related adverse health effects to specific food chemicals is neither robust nor settled. FDA continues to monitor the food supply, evaluate new science, and take action when we find that a chemical causes a food to be unsafe.

The workload in the food chemical space has increased and become more complex. There has been a proliferation of new scientific data and methods, increased development of new food ingredients, technological advancement in new sustainable food contact materials, and other innovations. There are also important gaps that need to be addressed as we undertake the work to strengthen our food chemical safety activities. We know that use patterns and use levels of chemicals and ingredients have changed over time, so we need updated exposure and safety data, including from industry, to support our reassessment work. Access to these data would allow FDA to take any necessary regulatory actions in a timely manner to protect consumers and help ensure food safety.

Closing

All people in this country should be able to live better, longer, and more productive lives—free of the burden of preventable food and diet-related illness, disease, and death. Giving people nutrition information via labeling, and improving the quality of our food supply, are of paramount importance. Change cannot happen soon enough.

Nutrition labeling is an important tool, but we need more than one lever to help Americans build healthier diets. We must continue to learn more about UPF, develop a stronger chemical safety review program, and build on the success of other nutrition initiatives like updating the "healthy" claim and sodium reduction.

Finally, when it comes to food, FDA shoulders an enormous responsibility, but we do not act alone. Improving the food supply and advancing nutrition is a shared responsibility. Industry must also do more to offer healthier foods; it is in everyone's best interests for the U.S. food supply to be a source of wellness. We at FDA are firmly committed to working with this Committee and Congress, with our regulatory partners, and with all of those who play a role in the nutrition of the U.S. food supply, to tackle head-on the challenges we face in our increasingly complex food system.

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[10] *https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/public-meeting-development-enhanced-systematic-process-fdas-post-market-assessment-chemicals-food*.

Thank you for the opportunity to testify today. We will be happy to answer your questions.

[SUMMARY STATEMENT OF ROBERT CALIFF AND JIM JONES]

This is an important time to testify before this Committee to discuss the Agency's efforts to reduce the chronic disease burden in America and the role our nutrition initiatives, such as the proposed front-of-package labeling rule, contribute to these efforts. The food we eat is contributing to America's title for the lowest life expectancy among large high-income countries. Nearly everyone knows and cares for someone with a chronic disease: six in ten Americans have at least one chronic disease, and 4 in 10 have two or more chronic diseases. This burden translates into astronomical health care and economic costs.

While there are myriad factors influencing health, the science is well settled to support that poor nutrition—including insufficient consumption of fruits, vegetables, and whole grains, as well as excessive consumption of saturated fat, sodium, and added sugars—increases the risk of diet-related diseases. Consequently, improving the American diet to help ensure food is a vehicle for wellness requires a whole-of-government and whole of society effort, including serious action from industry.

The clear association between ultra-processed food (UPF) and negative health outcomes is cause for major concern. While there is still much to understand, UPF are often high in saturated fat, sodium, and added sugars and there is already substantial evidence of harm when these nutrients are consumed in excess. FDA is not waiting to act where the evidence is clear. Establishing a front-of-pack (FOP) nutrition label could be a landmark policy. Displaying certain nutrition information right on the front of a package would allow Americans to quickly and easily identify how foods can fit into a healthy dietary pattern. FDA has done extensive research, analysis, and drafting, using all available tools and resources, to support a proposed FOP nutrition labeling rule so that it can benefit consumers.

In addition to front-of-package nutrition labeling, FDA is working to reduce sodium across the food supply and update the "healthy" claim. FDA is already seeing progress toward its sodium reduction targets and recently released data show sodium intake levels have decreased.

Another common characteristic of UPF is the presence of certain additives, such as flavors or colors. FDA is committed to leading the way on food chemical safety. Under the new Human Foods Program, we are leveraging the agency's scientific expertise and developing a more nimble and systematic approach to evaluating chemicals in the food supply.

All people in this country should be able to live better, longer, and more productive lives—free of the burden of preventable food and diet-related illness, disease, and death. Improving the food supply and advancing nutrition is a shared responsibility. Industry must also do more to offer healthier foods. FDA is firmly committed to working with this Committee and Congress and with all of those who play a role in the nutrition of the U.S. food supply, to tackle head-on the challenges we face in our increasingly complex food system.

The CHAIR. Thank you very much. Mr. Jones, did you want to add anything to that or——

Mr. JONES. No, thank you.

The CHAIR. Okay. Thank you again, Dr. Califf. I agree with much of what you said in your testimony. I agree with much of what Senator Cassidy said, but the problem is that the issue we're talking about today is not a new issue, is it? 2010, the National Academy of Medicine recommended that the food and beverage industry be required to put nutritional labels that the American people could easily understand on the front of their packages.

According to the CDC, the rate of childhood obesity in America has tripled since the 1970's. And from where I'm standing here, the FDA has not responded in any way with the urgency of the crisis. How long does it take to put a bloody label on a product? And by the way, we'll talk about that in a moment. I don't know if you're

going to be telling us after years and years of research and focus groups, what that label will look like.

But the bottom line here is, I would like you to tell me why when countries around the rest of the world with fewer resources than we do, are able to put labels on their product warning parents about the dangers of those products to their kids, how come the most powerful and wealthiest nation in the world is unable to do that?

Dr. Califf.

Dr. CALIFF. With your permission, I'm leaving soon.

The CHAIR. I heard that.

Dr. CALIFF. Not from this meeting, but from my job. So, I'm going to provide editorial comments and Mr. Jones can provide you a lot of facts. You asked how long does it take? Let's talk about tobacco. We were instructed to do that many years ago. We have lost in court on that issue, and we're finally winning now, it looks like.

But the point I want to make is what sounds simple given the current state of judicial affairs, First Amendment rights, the fact that corporations have the same rights as individuals, every little thing we do, unless specifically, in detail, instructed by Congress, we—it's not just that we lose in court, but we lose years when that happens——

The CHAIR. Let me—yes, again, I apologize for interrupting, but don't have endless amounts of time. I understand all that. But are you going to tell us with a straight face that you have become—you have come before this Committee and the American people and say, "Hey, we have a major, major crisis. We are losing lives. We're spending huge amounts of money. People's limbs are being amputated. We have got to act." And have you pointed a finger at those people who are the cause of the problem? Have you had the courage to take on a very powerful food and beverage industry?

There are 15 teaspoons of sugar in this product. How many parents in America know this when they give it to their kids and say, "Here, have a Coke. Go out and play ball." Have you done your job? And your predecessors, not just you, have you done your job in alerting the American people to the danger and rallying Members of Congress to stand up to the special interests who are causing these problems?

Dr. CALIFF. With all due respect, I've been working on this problem for all of my career. This is what I've done, and I think I have talked about this very specifically. I think we all wish that we had gotten to the goal sooner that you described. I'm not contesting that.

But I do believe in an appropriate discourse with this Committee. We need to carefully reflect on the issues in play right now that would allow this to happen. And I'm really heartened to hear the bipartisan support for this because much of what we tried to do, frankly, gets blocked along the way.

The CHAIR. Let's be honest here. The food and beverage industry spends hundreds and hundreds of millions of dollars on lobbying and on campaign contributions. You tell me the role that they are playing in destroying the health of America's children.

Dr. CALIFF. Well, I'm not going to contest your comment about the amount of money spent on lobbying. I think it's probably accurate. I don't have figures on that. But a lot of the changes that those of us who are interested in better health would like to make are blocked at the level of legislation for reasons such as——

The CHAIR. But I'm——

Dr. CALIFF [continuing]. You have to tell me.

The CHAIR [continuing]. Still not hearing you. What is the reason that our kids are unhealthy? What role do these this industry play? Even now, you're getting out of office. Are you prepared to tell us that this Committee, this Congress, needs to take on the food and beverage industry whose greed is destroying the health of millions of people?

Dr. CALIFF. Well, I'm not going to castigate the people that work in the food and beverage industry. What I'm——

The CHAIR. You're not?

Dr. CALIFF. No. What I will say——

The CHAIR. That is your job.

Dr. CALIFF. No. It's not to castigate. It's to point out how to make progress in this area. We have an industry that if you tried to change it overnight, there are farmers all over the United States who would not be able to grow the crops they're currently growing. So, there needs to be a plan, and it needs to be implemented in a mature, thoughtful way across the country. I'm 100 percent in favor of change.

The CHAIR. The Academy of Medicine in 2010. How many years does it take to do it? 14 years is enough time? How many kids have died and gotten sick during those 14 years?

Dr. CALIFF. It's not just kids, it's adults, of course. And I want to see it change as much as anyone, but we have to do it in a way that considers all the factors——

The CHAIR. Protecting interests of——

Dr. CALIFF [continuing]. That are involved to make a change.

The CHAIR [continuing]. The food and beverage industry.

Senator Cassidy.

Senator CASSIDY. I will allow Senator Tuberville to go first.

Senator TUBERVILLE. Thank you, Mr. Chairman. Thanks both for being here. We can, obviously, tell by all the young people in there, and even my two boys at home, they really got into this past election because of food safety and health. Because most of our kids are a lot more into health and nutrition than we were growing up. And it's really gotten out of control.

I want to ask you about Red 3 and Red 40, both of you, and get your comments on this. It's not a conservative or a liberal standpoint. I think we all need to understand as a group about how we've gotten to this point. The FDA has a position that food coloring like 40 are safe for our kids' ingestion. The both of you stand behind that?

Dr. Califf.

Dr. CALIFF. I'm going to refer that to Mr. Jones. Okay.

Mr. JONES. We have not evaluated Red 40 in over a decade, over a decade ago.

Senator TUBERVILLE. Wow. We have not?

Mr. JONES. We have not. We at FDA, we have not evaluated the safety of Red 40 in over a decade. So, over a decade, that was the conclusion that FDA made.

Dr. CALIFF. But we have evaluated—we are in the process of evaluating Red 3, and you may want to comment on that.

Senator TUBERVILLE. Well, let me say this. Red 3 has been known to cause cancer in cosmetics, but we still allow it to be put in our food. I don't understand that. Go ahead.

Mr. JONES. Red 3, we have a petition in front of us to revoke the authorization for it. And we are hopeful that within the next few weeks, we'll actually—we will be acting on that petition and a decision should be forthcoming.

Senator TUBERVILLE. Tell us that process. How does that work, the timeline? If we know something's deadly for anybody that ingested, how, how do we continue to just study that and not say, hey, enough's enough?

Mr. JONES. Red 3 presents an interesting example for us. It is actually known to be cancer in laboratory animals, rats, but the scientific consensus is that the mechanism of carcinogenicity in rats is not applicable in humans. However, under the FFDCA, which is the law that we implement, any chemical that is shown to be carcinogenic in animals or humans, or should I say humans or animals, cannot be authorized by FDA. It's called the Delaney Clause.

Even though we don't believe there is a risk to humans under the Delaney Clause of the FFDCA, red dye, because it is known to cause cancer in laboratory animals should not be authorized. And so, that is what has challenged FDA for many years, is how to manage around the Delaney clause, where you have a scenario where, although there may be cancer evidence in animals, there is also evidence that is not harmful to humans.

Senator TUBERVILLE. I hope the FDA feels a responsibility to humans. Dr. Califf, you've probably heard quite a bit about this for the last 4 years that you've been serving us. Has this been a priority? Because we hear it constantly about the dyes. I mean, dyes are just coloring. It has nothing to do with the taste or anything like that.

Dr. CALIFF. Yes. A couple of things, but, so first of all, it is a priority. And I want to point out, listen carefully to what Mr. Jones said. We don't have data in humans that Number 3 causes cancer, but we have it in laboratory animals. And so, this gets complicated. And I want to remind you of what it takes to demonstrate that a substance that people eat causes cancer. You have to study a large number of people over a long period of time because if something caused cancer right away it would be obvious.

But in these cases, you need something different. And I want to point out, we have a very small staff that can do this based on the budget. We have repeatedly asked for better funding for chemical safety. I brought Mr. Jones in to head the Human Foods Program

because of his history of working on environmental issues. I think it is a huge priority. He's an expert in this. Please look at our request for funding for the people who do this work. Remember that when we do ban something, it will go to court. And if we don't have the scientific evidence, it won't stand up in court. We will lose in court.

Senator TUBERVILLE. Okay. I want to ask you this, and I think everybody in here wants to hear the answer to this question. We all hear Europe uses different dyes because they've come up with their evaluation that it does cause problems for humans. Do we have a different review system than they do about food dyes, or anything put in food?

Mr. JONES. The biggest distinction between the U.S. and Europe is that they have been doing post-market review of chemicals now for over 20 years. In the FDA, although we have authorization to do post-market reviews, there's no statutory mandate to do them. One of the things that Dr. Califf mentioned is that as part of this reorganization, we are dedicating an entire office whose job is to do post-market chemical reviews.

But we are several decades behind Europeans and our Canadian counterparts because they have legal mandates to reevaluate chemicals that have been authorized at some point in the past. We don't. But we are going to undertake it, but we are going to definitely struggle with the resources necessary to do that.

Dr. CALIFF. There's a real lesson here from—I don't know if you eat Froot Loops. I grew up every once in a while, eating Froot Loops. But there's a real lesson here, and I don't—I haven't verified this myself, but it's widely written that when the dyes that make Froot Loops bright were taken out for the reasons that you give, the sales went straight down and they were put back in.

As long as we have a consumer driven system where what people like in the short-term is what drives the system, unless we have help from you-all that is clear direction from Congress, particularly given the recent Supreme Court decisions, it's going to be really hard for us to mandate how things come off. Just a point I'm going to make over and over and I thank you. I apologize, but I think it's really important that we work together on this.

Senator TUBERVILLE. Thank you. Thank you for your points.

The CHAIR. Senator Murray.

Senator MURRAY. Thank you very much, Mr. Chairman.

You know, as we all know, chronic diseases, we've been talking about heart disease, diabetes are the leading cause of disability and death in America. And it's all too common as the Chairman talked about. We have about 1 in 10 people in Washington State, about 1 in 10 Americans suffer from diabetes. So, we really do need evidence-based approaches to advance nutrition and to prevent and treat chronic diseases like diabetes.

Dr. Califf, earlier this year, I got to hear directly from you at our Senate Appropriations hearing about your plans to stand up the new Human Foods Program, including a new Nutrition Center of Excellence. Can you or Mr. Jones talk about how FDA is utilizing research from NIH and other Federal agencies to scale up what we

know about preventing and treating chronic diseases like diabetes, and to better inform our food policy?

Dr. CALIFF. Quick editorial point of view and then Mr. Jones can give the details. This is the largest reorganization in our history, as far as we know. 8,000 people changed. It was widely embraced. Maybe contrary to some statements I've heard about Federal employees, widely embraced by the workforce at FDA to do this reorganization because people recognized they needed to focus on this and a better structure to do it. It involves the entire inspectorate at the entire Human Foods Program.

As many people requested, we brought in a leader, Mr. Jones, to head the whole thing up. So, it's a very high priority. A quick comment on NIH, and it's very important, that we not tell at FDA, NIH what to do. There is a lot of nutrition research at NIH, but it's spread across all the disease and body parts areas, as I call it. We very much need this sort of basic research on obesity per se as an element.

There's some tremendous research by, particularly, our investigator named Kevin Hall on ultra-processed foods. Very important to us. But we're going to have a big meeting next month, or this month, I guess, now, between FDA and NIH on the research agenda. So, look forward to that.

Senator MURRAY. Mr. Jones.

Mr. JONES. One of the reasons we established a Nutrition Center of Excellence was because we realized that we were not going to have the kind of resources that ideally one would want. And so, the center is going to work with other entities within the Federal Government, including NIH, but other entities in the Federal Government, in particular USDA, and as well as universities, to make sure that we are fully taking advantage of and collaborating around the research portfolio on nutrition across the country.

We work very closely with NIH, and as Dr. Califf said, in 2 weeks we are co-hosting with them a research symposium that's going to be focusing on what does the research agenda for ultra-processed food need to look like.

Senator MURRAY. Okay. I also want to ask you, while you're here, about the Modernization of the Cosmetics Regulation Act that we passed. For a long time, harmful substances have made their way into makeup, lotion, hair care products, and many other products that people use every day. And the FDA had no power to take any action.

Back in 2022, we passed my bipartisan Modernization of Cosmetics Regulation Act, known as MoCRA, which empowered FDA, finally, with the tools that needed to better ensure cosmetic products are safe. It was the biggest change to FDA's authority to cosmetics since 1938.

Now, it's been 2 years since the enactment, and I wanted to hear from you on how implementation is going, and how the FDA is working to improve the safety of personal care products. The law requires—actually, required FDA to issue good manufacturing practices for facilities that manufacture cosmetic products. Since

it's been 2 years, the FDA has not put out any good manufacturing practices. So, tell me where we are with this?

Dr. CALIFF. Sure. So, first of all, I want to thank you. I worked on this in 2016. It took a long time to get the legislation, and it's much appreciated and much needed. There's actually a good partnership with industry to make this happen, but we have stood up the registration of facilities and products.

Some Americans may not believe this, but there was no record of what cosmetics were being put on the market before this. And we've now got a listing and also a complaint system that didn't exist. When there are adverse events, they can be sent. So, GMP is on the list to work on. And I know that's not a great time to talk to Congress about budgets, but the budget what was allocated to this was a small fraction of the estimates by everyone involved of what it would take to actually meet the requirements of Congress.

This is going to need to be looked at in terms of if we want this to get done in a timely fashion, there actually is time and material of qualified experts to get the work done. We're doing everything we can to use internal resources. Like, we use the drug complaint system to register adverse events. That saved a lot of money compared to doing it de novo.

Senator MURRAY. Well, I'm out of time, but I just want to let the Committee know. I'm going to be following up on this, making sure that FDA is very aggressive implementing the law that we passed 2 years ago.

The CHAIR. Senator Cassidy.

Senator CASSIDY. Thank you both. First, Dr. Califf, I'm just going to go far field from nutrition, but it's just so topical. Hurricane Helene has disrupted the production of saline fluid. I'm a physician. I hear from my local hospitals that there is down to a one-to-two-week supply of saline and other IV fluids.

You may tell me that you have to go back and research this, but I have a constituent who has a FDA-approved plant elsewhere in the Philippines. And I just mentioned him because I learned from him, but others have the same thing, and they cannot get an EUA to bring these products in. And indeed, they can't even hear from FDA as to why they can't get the EUA. It's always kind of like, we'll get back to you.

Now, we need resilience. It kind of reminds me of the delay in getting infant formula in. Are you prepared—and you're not, I didn't prepare you for this question, but do you have any ability to comment on this?

Dr. CALIFF. I'm a little bit prepared. And let me tell you, I'm hyper aware of this. With permission, I have a brother who has pancreatic cancer who was just in the hospital. I was there and he got one of the two bags of IV fluid he was supposed to get because of the shortage. So, I'm very aware of it. I'll say that we have been opening up—in order to allow a foreign facility in, we have to make sure that it's going to be safe.

Senator CASSIDY. No, but if it's FDA approved already, at least I'm told, well, that seemed like that would be a——

Dr. CALIFF. Well, that we'd have to get back on the specific incident, but FDA-approved facilities could cover a wide range of possibilities of whether it's the actual product, how long ago was it, et cetera. So, staff really have to make sure that when we import things, that it's safe.

Senator CASSIDY. Can I follow-up with you afterwards?

Dr. CALIFF. Yes, please do.

Senator CASSIDY. I'd appreciate that.

Next, and I won't—if I interrupt you, it's not to be rude, but just to kind of get through some questions. One of FDA's primary responsibilities in food safety is inspecting. And I understand that FDA continues to struggle to conduct regular inspections at the pre-pandemic pace. At what point will we back, or what steps are you doing to get back to these more regular safety inspections?

Dr. CALIFF. First of all, let me say—I mean, as you all know, the day I was confirmed was the day of the Abbott recall. That was my welcome back to the FDA. And it was immediately obvious that we had many, many good people working between the Human Foods Program and the Inspectorate who were in the wrong configuration. And this has led to this massive reorganization.

A major part of the reorganization is to get more, we call them investigators—you would think of the term inspectors—out in the field and make sure that they are highly valued. Among the many difficulties we have, and I used to manage a global clinical trials organization that did studies of therapeutics, our investigators are flying government-style and staying in hotels that their colleagues who are doing inspections for the industries are not staying in. So, we're really upgrading the status of the investigators so that when they arrive at a place, they're prepared, and ready, and building information system.

Very quickly, I know we're going to be short on time. We want an information infrastructure so that when they're in a place, they are guided. AI is a big part of this. Guided to focus their attention where it's needed so they can do more inspections.

We're going to get into, I know later in this hearing, the state relationships. The states do a lot of inspections and there's also intelligence from other countries that doesn't substitute for an FDA inspection, but can be very helpful. So, we're working on every part of that to increase the reach and magnitude of inspections.

Senator CASSIDY. Now, but it sometimes begs the question because before these positive steps, you had a higher rate of inspection, and after these positive steps, you continued to have a lower rate of inspection. It begs the question of like, were the steps positive?

Dr. CALIFF. Well, we had a lot of loss of key people during the pandemic. Everything I've told you about the lives of the inspectorate and then flying around in the pandemic, not exactly a choice job compared to other options. It really took dedicated——

Senator CASSIDY. If you look at your decline in investigator/inspector workforce, what percent of decline have you had?

Dr. CALIFF. I can't give you the exact number. We can get back to you, but I can tell you it's on the way—we were actually losing net people.

Senator CASSIDY. But then let me ask you, again.

Dr. CALIFF. But now, we're now on a positive slope.

Senator CASSIDY. Limited time. So, to what degree can you attribute the loss of workforce to the decreased inspections? Is that the sole thing, or?

Dr. CALIFF. Well, during the pandemic there were other factors. Like, we had to be able to get——

Senator CASSIDY. But now post pandemic?

Dr. CALIFF. Now, I think it's just a matter of personnel and time allocated. But I know we're working with your people on some details on this.

Senator CASSIDY. I'm just going to ask you, if you don't mind, then later, as a question for the record, provide us the metrics that you're using to judge the kind of progress of this. Is it all personnel? That's understandable. If it's still system-related, despite these changes in systems, that would be something for us to know.

Dr. CALIFF. Again, just very quickly, a lot of it is personnel. But I describe some other system characteristics that are characteristics of the government that make it hard for the inspectors to do their work. It's going to take us a while to fix those because these are government-wide policies.

The CHAIR. Thank you.

Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman. And Dr. Califf, thank you for joining us today. It's critical that the FDA provides consumers with clear and accurate nutritional information at the grocery store by enforcing labeling standards and upholding the Agency's own rules for standards of identity.

For years, I have worked with farmers and dairy processors to address the misuse of terms like "milk" and "butter" on plant-based foods. In addition to introducing the DAIRY PRIDE Act, I've repeatedly asked the Agency to enforce labeling standards, and even secured funding for the FDA to dedicate to this purpose. So, I'm very disappointed by the lack of progress made at FDA.

In 2023, the FDA published draft guidance that enables misleading product labels to remain on store shelves. The update merely provides voluntary guidance on nutritional labeling to plant-based processors, violating both FDA's rules for standards of identity and the Administrative Procedures Act. It's hard to believe that plant-based alternatives would willingly highlight the nutritional disadvantages of their products compared to real milk.

We're here today because of the health of American families and children is at risk due to insufficient nutrition. Studies consistently show that consumers mistakenly believe that plant-based alternatives are nutritionally equivalent or even superior to dairy products.

At the same time, the inappropriate substitution of non-dairy alternatives has been linked to a range of health issues in children

and in infants. So, understanding this, how does the FDA justify the voluntary approach outlined in the guidance?

Dr. CALIFF. I guess it's only appropriate, this is our first conversation, I guess this will be our last, on the same topic. And I'm going to ask Mr. Jones to give the details here. Our narratives are not exactly the same, as you know. But, Mr. Jones?

Mr. JONES. Sure. Thank you, Senator. So, there are two issues I think you're raising. One is using the term "milk" and the other one is the nutritional equivalence. And I'll try to address both of them. So, if a plant-based milk alternative is labeled as milk instead, for example, soy milk, that would be a violation. That is not allowable. The law doesn't prohibit the term "milk" in the labeling of such products. So, as so long as the name itself is not misleading. And we have a fair amount of research—well, a compelling amount of research that consumers are not misled.

The CHAIR. I'm sorry, Mr. Jones, can you talk into the mic. I'm not hearing you.

Mr. JONES. I'm sorry—consumers are not misled by using terms such as soy milk or oat milk. They understand that it is not milk. They're purposefully seeking such products because they're not milk. So, on the issue of using the term milk, you have to use it, you have to characterize what it is derived from. So, it has to say soy milk or oat milk. You can't just say milk on such a label.

As it relates to nutritional equivalence, the guidance that you described, we were taking comment on that. And as you pointed out, we said we encourage manufacturers of these products to identify that they are not nutritionally equivalent to a dairy product. We have gotten a fair amount of comment that is not adequate, and then we are taking that comment under consideration.

Ultimately, I can't say where we will land on that issue, but the nutritional equivalence issue is very much on our radar. And as I said, we've gotten a fair amount of comment along the lines that you've described around nutritional equivalence.

Senator BALDWIN. Well, it would be cleared up if they didn't use the term milk. Right? But let me go on. We are also seeing a rise in the availability of cell-based, lab-grown products using dairy terms in stores. Does the FDA have a plan to ensure that these products are labeled in a clear way that avoids any additional consumer confusion what's already a complex marketplace for dairy products and plant-based alternatives?

Dr. CALIFF. Well, when we talk about a cell-based product, it's really important that we know exactly which one because, in general, we regulate the safety of these products. But USDA regulates the label of these products. And so, we have to know which ones you're talking about. But I think above all else, it's going to be important that the labels accurately reflect what the product is. And so, we'd certainly agree that whether it's us or USDA, that needs to be taken into account.

The CHAIR. Senator Hickenlooper.

Senator HICKENLOOPER. Thank you, Mr. Chair. Thank both of you for your service. I was at a round table in Colorado a while ago, and throughout, one of our constituents referred to Dr. Califf

which I thought was a really—given the fact that he still has somewhat of an accent, I thought that would be an interesting way to magnify that.

I do appreciate the fact because you have been resilient in seeking more funding. And many of the complaints that we're having are because there's a clear manpower shortage. I'm not saying everything is resolved that, but certainly, a significant part of the complaints we've heard so far this morning it's a lack of people being able to respond to inquiries, to complaints, to opportunities to redress some of these health-related issues.

Let me talk a little bit about sugar connections and dementia. Obviously, you talked a little bit about how almost three-quarters of our food is made up of ultra-processed foods, and recently the researchers are starting to see a possible connection between ultra-processed foods with higher rates of diabetes, and then later in life, there seems to be a connection to dementia.

I understand the limitations of science, and that's one of the big challenges for you-all, that every time science leads you in one direction, the unbelievable pressures of profits in corporate quarterly earnings pushes you or presses back in a powerful way. But even as the science is evolving, there is pretty good evidence that diabetes leads to a higher rate of inflammation, damaged blood vessels, which all seem to be a part of the impairment of our cognitive efforts as we get older. Again, this is already a problem, could become much more severe.

Dr. Califf and Mr. Jones, has the FDA come across this connection while conducting research on the impacts of sugar, and how should the FDA and other public health organizations be responding?

Dr. CALIFF. Well, this relates back to Senator Murray's question, because as you know, we don't have much of a research budget. We're not a research organization. So, we're very dependent on other entities, particularly NIH, but also the industries that are regulated.

I want to come back to comment on that in a second. But there's no question. I mean, this is what I do for a living. I'm a cardiologist. I've been talking about this for 30 years, and the data's getting stronger and stronger. I happen to have two sons, as you know, that live in Colorado and four grandkids. You're in a state where it's in the culture to eat better. It's normal in Colorado to eat healthy food. I'm from South Carolina, so I feel like I can say this. It's not so much in the culture in South Carolina.

You see it in the difference. There's a report last month. We're now up to a 24-year difference in life expectancy, depending on where you live in the United States. Senator Cassidy's from Louisiana. No offense, but very similar to South Carolina in eating habits. And so, the evidence is very clear that—and I don't think any experts disagree, there's some general things you should do. Exercise, eat less fat, sugar, and lower sodium. And as long as we're in an argument about whether the government should mandate things or whether people should have a choice, and that's not resolved, we're up to the culture of the place that you live.

Now, one final comment about your question about research. One noticeable thing to me, and I readily admitted when I took the job, I was not an expert in food. I've learned a lot in my two stints at FDA. But one really big difference is when the medical products industry does research, by law, if it's done on human beings, it is made public and we have access to it.

We look at the raw data and analyze it ourselves at the FDA. The food industry does massive amounts of research that we have no access to, and we don't know what they're doing. We don't know what's guiding their decisions. And it would be a lot better if the research that was done on human beings by the food industry was made public.

Senator HICKENLOOPER. We agree. I'm going to throw out another question. You have to answer quickly because I'm about out of time. But the University of Colorado, Denver Diabetes Research Center runs a program to recruit young faculty into diabetes-related research, and it's estimated that, obviously, the number of type 2 diabetes patients is going to rise astronomically in the next 40 years, maybe 70 percent.

How do we prioritize the research that—and as you will say, the NIH is doing all these different pieces of research that are all disconnected, whereas we see diabetes or obesity really being a common connector. We had a hearing yesterday with the Global Down Syndrome Foundation, looking at all the different places that we're not spending enough doing enough to interconnect all that research.

Dr. CALIFF. Well, again, far be it for me to tell NIH how to allocate his research dollars. But I will point out diabetes is an interesting example because there's a National Institute of Diabetes and Digestive and Kidney Disease, NIDDK, which is very diabetes-focused. And I feel like they do a very good job. The general issue of a 16-year-old who's obese and might develop diabetes later and what to do about a normal human being who's not sick, doesn't have a disease yet, is a big issue that I think needs more attention.

Senator HICKENLOOPER. Thank you.

The CHAIR. Senator Murkowski.

Senator CASSIDY. Can I just interject real quick for a point of clarification? That 24-year difference you speak of is not entirely attributable to diet or to nutrition. It's many other things, for example, gunshot wounds. So, just to make that point.

Dr. CALIFF. Completely agree on, and much appreciated. And there's going to be a big presentation next month from the group in Seattle that generates all these statistics. I would really urge people to tune into that because it will cover all of the different intersection of all these issues that are creating these discrepancies.

The CHAIR. Senator Murkowski.

Senator MURKOWSKI. Thank you, Mr. Chairman. Gentlemen, welcome. Dr. Califf, you probably know I'm going to be talking about genetically engineered salmon. You're not going to be disappointed here this morning. But before I go to that question we are talking about, about access to healthier foods. And I know that we all rec-

ognize that in parts of rural America, certainly in places in my state, healthy food is hard to come by. It's expensive. And it is just a real challenge to make sure that people are getting the good, healthy, nutritious diet that they need.

They got subsistence food that are greatly helpful. But when you have a 24 pack of Costco water costing $99—I've got the picture on my phone—in the community of Glavin, I think it was. 99 bucks for water in a community that lacks just good, solid, safe drinking water. So, this contributes to—you got to get your liquids from somewhere else. And when it's cheaper to drink pop or you call it soda, I call it sugar water, we know what we're going to see. And we're going to see those health outcomes in those kids and in those families.

That is something that I think we need to do a better job in addressing, is how, how we are making sure that in rural areas, our kids and our families are not subjected to these food deserts or healthy food deserts.

Talking about GE salmon, and I have to take you back to the food labeling because this was what we had required. We wanted to make sure that there was labeling of genetic engineered salmon that was unambiguous in its labeling. We have this focus group that effectively comes back—this is last year—and it concluded that most focus groups participants struggled to grasp the scientific language used by the FDA.

You go back to the language. And for those of you who have no clue what genetically engineered salmon is, let me ask you if this makes sense to you. The fact sheet is out there about how GE salmon is different from other fish. It says, "GE salmon has been genetically engineered to reach a growth marker important to the aquaculture industry more rapidly than its non-GE-farmed, raised Atlantic salmon counterpart. It does so because it contains an rDNA construct that is composed of the growth hormone gene from a Chinook salmon under the control of a promoter, a sequence of DNA that turns on the expression of a gene from another type of a fish called an ocean pout."

What is that all about? Nobody knows. So, the question then, they say, well, it sounds a little bit concerning. It sounds not normal. And so, what we have tried to do is make clear that if the FDA is going to allow the sale of this genetically engineered salmon, that there is clear labeling requirements to differentiate between wild-caught and GE salmon. Do you think we're there yet, Dr. Califf, with a clear unambiguous?

Dr. CALIFF. There has been a precipitous decline in Native American and Alaskan populations in terms of life expectancy just in the last few years, which is even more dramatic than what we're seeing before.

Senator MURKOWSKI. The rise in obesity as you said.

Dr. CALIFF. Well, your point about water and access to healthy food in rural communities is especially important here. And I acknowledge that on the labeling, it would sure be better if we could come up with words that people can understand. I do take exception. You said no one understands it. What was described in that

label actually is scientifically accurate. And everything that's in the label is part of normal machinery in every living organism.

Senator MURKOWSKI. I get that.

Dr. CALIFF. But what could a consumer do with it? Your point is well taken.

Senator MURKOWSKI. If I am a consumer in the grocery store, that to me means nothing. Let me ask quickly about another concern. You've heard me talk about GE salmon for a long time. But now I'm concerned about cell-cultured seafood grown in a lab.

We've got Frankenfish over here, now we've got Petri fish. I know some companies are pursuing FDA approval for the cell cultured, but I'm curious about FDA's position about the future of cell-cultured proteins, and how lessons that we've learned about the confusion surrounding GE salmon can be applied here. So, if either of you care to comment to that.

Dr. CALIFF. I'll make a quick comment, and then I'd be very—actually, be very interested in what Mr. Jones has to say about this. You and I probably have a difference of view. Our climate is changing. We're seeing radical changes in growth patterns. Just an example right now is the pulp in oranges is a problem because of the climate changes in Florida, and we're going to need to take some action on that to fix it. So, I think exploring and learning about approaches to creating food, which is resilient to these kinds of changes in a global population, which is going to be in dire need of nutrition, is a very important thing to do.

Now, we've learned a lot about how to scientifically assess and deal with the manufacturing process. And so, I think we're going to get better and better at it. I don't know where it's going to end up, but I would love to have a food system that gave nutritious food at a low cost to everyone in the U.S. for sure, but just as importantly, ultimately, to global populations who are going to be driven out of their homes by the rising tides and the heat waves that we're now seeing around the world.

Senator MURKOWSKI. Well, and my time has expired, but I will just say to that point. A fish as a living species out there is different than an orange on a tree. And when these genetically engineered species get into the wild stocks and mix with them, then you have Native people those who rely on our wild harvest that have their fisheries jeopardized.

Dr. CALIFF. Well, I can testify that you know a lot more about this than I do. You caught the bigger salmon when I went salmon fishing with you.

Senator MURKOWSKI. Bingo. You're invited back.

The CHAIR. Senator Kaine.

Senator KAINE. Thank you, Mr. Chair. Dr. Califf, in your verbal presentation at the beginning of this hearing, you concluded by saying there's some challenges if the U.S. were able to do things that other nations do in the area of ultra-processed foods. Either because of they have a different legal climate, or they have different views about individual freedoms, then we might have more success in battling this.

I was intrigued by that, though that was not the questions I was going to ask you. But since you were referring to some things that other nations do, I thought I would just ask you; what are some strategies that are being pursued by other nations that are successful?

Dr. CALIFF. Yes. So, I actually think this is for so much of the things that have frustrated me at the FDA, this is the core issue. We have a unique stubbornness of individualism in the U.S. which is phenomenally great in many ways, but when it comes to public health, it's a real problem. Because other countries know that we're interdependent when it comes to public health. That is, if you present—and I'll just use my experience at Google where I worked——

Senator KAINE. But I really want to get to specifics, too.

Dr. CALIFF. Okay. So, yes, here's the example. If you want to influence someone's behavior to eat healthy food, you don't present them with a chart with a bunch of numbers on it. You show them a picture of a graphic image that has an emotional impact. That's what the advertising on the other side is doing. Froot Loop does not show commercials of one Froot Loop with all the constituents of the Froot Loop. It shows beautiful pictures of Froot Loops and nice people eating them with an emotional impact.

We're not allowed to do that. And even in some of our more recent dealings, we have been instructed that at the FDA, we just provide information. The one case that's an exception was tobacco, where we were instructed to do it. And we still lost in court the first time. It set us back 5 years.

Much of this has to do with the environment that people are living in. I mentioned I am Colorado-prone because of my family. People in Colorado are not as obese as the rest of the country, and they exercise more. So, if you're in that environment, you're going to be more likely to behave that way.

Senator KAINE. Have other nations already embraced front-of-package labeling of the——

Dr. CALIFF. Absolutely.

Senator KAINE [continuing]. Way the FDA's trying to do?

Dr. CALIFF. Not just labeling, but warning signs.

Senator KAINE. Warning signs. Here's one that I know is controversial, and I've heard arguments on both sides. How about programs like SNAP Benefits? A lot of SNAP benefits are used for very unhealthy foods. Do other nations that have supplemental food programs like SNAP Benefits?

Dr. CALIFF. I can't honestly say I know about the other—exactly what the other nations do here, but I know that this is a USDA program, as you well know. It's vitally important. We have so many children in the U.S. who can't afford their own their parents can't afford their own diet. And I know there was a battle over this issue last time around. It would be one of the most important things, I think, that could be done here. The U.S. Government has the purchasing power. So, why not purchase healthy food?

Senator KAINE. There are programs that do incentives for the purchase of healthy foods, but there's also some evidence to suggest

that even in the same neighborhood, families that use SNAP Benefits versus those who don't, the SNAP Benefit purchases are generally less healthy than those who don't use SNAP Benefits.

Dr. CALIFF. Again, and I hope I get asked about the weight loss drugs. I know we need to move on here.

Senator KAINE. All right. I'm going to ask you about that, since I have 1 minute 21 left.

[Laughter.]

Dr. CALIFF. Okay. What's going on here is that the food industry has figured out that there's a combination of sweet carbohydrate and salt that goes to our brains and is very—I think it's addictive. Now, that's my opinion. And I think it's the same neural circuits that are involved in opioid addiction and other kinds of addiction that we have.

They've studied this. Again, we don't have access to their research data like we do in the human medical products arena. And so, if you're a person without much financial means and you're walking into a grocery store, and the inexpensive ultra-processed food is half the cost of the fruits and vegetables and it's carefully configured to really hit that brain the way to think about this, if you ever tried to eat one potato chip, it's almost impossible.

There's a reason for this and there's a lot more research that needs to be done because we couldn't uncover the addiction circuits until the GLP ones came along because what they're doing is actually interfering with this circuit between the gut and the brain that tells you eat more. And there are actually three or four pathways involved here that are really fascinating that we're going to learn a lot more about. But here's a way to think about it. The food is probably addictive. And, again——

Senator KAINE. Engineered to be addictive.

Dr. CALIFF [continuing]. This is not an FDA policy. This is my opinion, having looked at it.

Senator KAINE. Thank you. Thanks, Mr. Chair.

The CHAIR. Let me just take a moment before Senator Braun goes. You just said the most important point of the hearing. You said that the food industry is producing products which are unhealthy and addictive. And the question, of course, that's exactly what's going on. What the hell have we done about it over the last 15 years?

Senator Braun.

Senator BRAUN. Thank you, Mr. Chairman. I would agree with that 100 percent. The whole system. And I've been on this Committee all 6 years. It's the one thing I'll miss in the U.S. Senate because it's the most important discussion, our well-being. And it's built upon no attention to wellness and prevention in expensive remediation.

It's evolved that way over the last 20 to 30 years, and the FDA happens to be at the most visible point of where you got to intercede. Is it worth it to keep pushing expensive drugs when we give no attention to wellness and prevention? I want to give you a little quickest. Done it several times on this platform. 16 years ago,

when I was sick and tired of hearing how lucky I was, my premiums are only going up 5 to 10 percent each year. Had 300 employees at the time. It's now five times that many employees imagine of the geometric cost of healthcare.

When I said, enough is enough, we built a system on prevention and wellness, created healthcare consumers out of my employees, and cut costs by way over 50 percent. Anyone in the audience not had a premium increase in the last 16 years on your health plan, may want to put an application into the company I used to run.

That is how much you can get done. If we get off the paradigm of where we've let huge corporations, food industry, especially the remediation business, which is driven by big corporate hospitals and insurance companies, keep driving the dynamic. When I gave my employees a free biometric screening, we cut diabetes off before it was going to become symptomatic. Any of the blood serum indicators that play into heart disease, you're catching it before it happens.

Why are we still in a system that has nothing to do with an ounce of prevention being worth a pound a cure? And you happen to be in the Agency that has to deal with it all the time in terms of what the new modality is. It's going to keep treating expensive remediation. Where do we turn the tide to where we make your Agency less relevant? Because you don't have to do as much of it because we're preventing it rather than trying to remediate it.

Dr. CALIFF. I just want to tell you how much I appreciate the way you framed that, because I was going to bring up you said we're at the forefront. My favorite article of all time in the medical literature in the *New England Journal of Medicine* from Alistair Wood is entitled, *Playing "Kick the FDA"—Risk Free to Players, but Hazardous to Public Health*. And it relates to exactly the—I urge you all to read it. It's a 14-year-old article, but it relates to what you said, and you've missed a lot of this discussion.

But this is a systemic problem that does need to be addressed and it would actually be great. I'm on record. I've been quoted on this. I've had this nightmare that I was head of this agency that my great grandkids read about called the FDA where a society let people gain essentially a pound of weight every year and then to fix it, they invented a drug at $20,000 a year to try to deal with it. And that would be a very bad legacy to leave behind. So, I hope this will be fixed.

I do want to point out to you this, you are about to become Governor of the state as I know it. That doesn't look good in this regard. And so, I think a lot of people are going to be watching whether you can change this. You said it well, if you're running a health system today, and I used to be an executive in a health system, you make your money by doing expensive procedures after the sickness.

Senator BRAUN. Glad you brought up that point because here you're on the pulpit. Finally, Senator Sanders and I have put out a transparency and competition bill because my last question's going to be for Mr. Jones. I talked about wellness and prevention. The other key element is on the scratches and dents for those that can afford it. Insurance was never intended to be more than indem-

nification. Now you got MBAs running it and it's about high premiums and keeping claims low. That's got to change.

How important, Mr. Jones, would it be for all of us to have a little skin in the game, to have at least the incentive to shop around for when we need some type of prescription or modality? And do you think that the way we've evolved to where it's been an atrophied healthcare consumer that wants immediate results and wants either the government or their employer to pay for it, how much importance is it going to be to where there's a little skin in the game on the part of all of us when it comes at least to healthcare maintenance on the minor level?

Mr. JONES. Well, my jurisdiction of FDA is the food side. So, I think that Dr. Califf is probably better equipped to answer that question.

Senator BRAUN. Go ahead, Dr. Califf.

Dr. CALIFF. Just opinion. I think my read of the cognitive behavioral literature, which is extensive on this, is that people need choice, but if you give them too many choices, they can't figure out what to do. And so, we've got to find a balance of options, but not so many that people are lost and then they just revert.

Senator BRAUN. That's a good point in the one, two punch of what's worked now for 16 years. I know that's part of the solution. It makes costs for government go down through Medicare, and Medicaid, and the private side as well. I think it's something where we can get the best of both worlds. Thank you, Mr. Chairman.

The CHAIR. Thank you.

Senator Hassan.

Senator HASSAN. Thanks so much, Mr. Chair, and Ranking Member Cassidy, for this hearing. And it's good to see you, Commissioner, and I thank you for being here today.

Dr. Califf, food companies spend over $1.5 billion a year targeting children with advertisements for unhealthy nutrient-poor foods. And we've been talking about the impact of that. These companies also target parents by marketing their products with misleading health claims. For instance, many high sugar beverages are marketed as all natural options for children, which can mislead parents into thinking that the products are somehow a nutritious choice. So, Dr. Califf, what is the FDA doing to address misleading junk food advertisements that target children and their parents?

Dr. CALIFF. Two-polled response to that. First of all, the term "healthy" is a very important term, and it's way out of date. And we are in the process of redefining the term healthy and putting it there for people with a nice-looking symbol so that people can readily identify what a generally healthy food is from one that's not. So, that's important.

I've already discussed, I think, the difficulty we have with advertising in general. We are very restricted in our ability to restrain people with First Amendment rights. And the advertising industry is very clever at how to do this in a way that's very hard for us to enforce.

Senator HASSAN. I do understand that. I hope you are working across government with some of the other agencies that might have more different authorities than you do.

Dr. CALIFF. One of my things for today and highlighted by recent Supreme Court decisions is there's nothing better than a very explicit law by Congress if you want us to take this on.

Senator HASSAN. Understood. I do think there are some options you have for misleading or truly false statements if you work with other agencies. You mentioned that the FDA is working on a proposal to require food companies to display easy to understand nutrition information on the front-of-food packages. This change would help people identify healthy food options on the shelf.

I understand that the FDA researched options for new food labels, but did not test how the new labels might impact teens who often make food purchases independently from their parents. So, how will the FDA ensure that any updated food packaging rules also help young people make healthier decisions?

Dr. CALIFF. I think Mr. Jones and I both would view that in the process of researching this. Studies and teens are important, and those are going to follow-on as we go through this. But all is not lost because studies were not done directly in teens. And Mr. Jones has a set of stats here that I think are important to get on the record.

Senator HASSAN. Sure.

Mr. JONES. Yes. The design of the studies that we were relying on were done several years ago. And the choice was made not to include children or teenagers. The basis for that were a couple fold. One, was literature indicates that the most influential factor in children's diet are parental behaviors. And reinforced by that, was that about 4.26 percent of all sources of food for children 12 to 17 are convenience store foods which is basically where they're going to access when they're doing the shopping. And so, the combination of the two led the Agency to choose not to include teens in the sampling that we did.

Senator HASSAN. Okay.

Dr. CALIFF. Since I'm leaving, I'm Okay to say this. If we had a bigger budget, we would've studied a lot more things.

Senator HASSAN. No. That is helpful feedback, to be sure, and I appreciate the work that you have done. Dr. Califf, one more issue. You and I have talked about this before, and I have stated here before that the FDA played a role in fueling the opioid epidemic that we have today. And that the FDA still has much work to do to ensure that something like the opioid epidemic never happens again.

I want to focus on a drug labeling issue that we've discussed for years. The FDA permitted opioid labels to claim that opioids were safe and effective for long-term pain management, despite evidence showing the grave danger of these opioids over the last several years. I've called repeatedly upon the FDA to remove these baseless claims from the opioid labels.

Last year, the FDA finally released new labeling rules for opioids, which will help doctors and patients alike understand the

risk of opioid addiction. One year later, have all the manufacturers complied with the new rule and updated their labels?

Dr. CALIFF. I'll have to get back to you on whether it's all, but we're 100 percent sure that great progress is being made. But I'd have to get back because I don't have the specifics on that. This is very important.

I also want to mention I was very much in favor of comparative effectiveness requirements for opioids before a new one could get on the market. But we lost that with the Congress.

Senator HASSAN. Yes.

Dr. CALIFF. It's one of the—my theme today is we need to work together.

Senator HASSAN. Yes. We do indeed. But we also need to make sure that all of you have the ability and protections to exercise your scientific judgment effectively. Thank you, Mr. Chair.

The CHAIR. Senator Budd.

Senator BUDD. Thank you, Chairman. Again, thank you all both for being here. In November, the American people that made their voices heard, they want to restore trust in agencies like the FDA, and make it easier for Americans to live a long and healthy life. The guiding principle of the FDA should be to provide the public with either with clear information so that individuals can make informed choices for their own health.

FDA has broad discretion on when and how to enforce the Food, Drug and Cosmetic Act based on the level of risk it perceives, and when a violation might pose a risk to public health. Too often, FDA acts arbitrarily and inconsistently. So, here's an example. When the FDA claimed the authority to regulate electronic cigarettes, it did not inform manufacturers of additional requirements until after the deadline to file and the application was due, essentially creating a de facto ban.

Commissioner Califf—and again, congrats on Duke's win over Auburn last night. I know Tommy or Senator Tuberville has already come and had his comments. I'm not sure that was mentioned or not, but since he is not here, we can say congrats. So, glad you're here as a fellow North Carolinian.

As new regulations like the front-of-package labeling are considered, how is the FDA ensuring consistent and timely guidance in that any enforcement actions are done in an impartial manner?

Dr. CALIFF. First of all, yes, if I look a little sleepy, I did stay up and watch the entire game and the post-game interviews, which were priceless. I didn't want to rub it in with Senator Tuberville that happened and Senator Marshall's left. But we lost to Kansas, as you may remember, unfortunately.

I mean, Senator Budd, you just actually articulated something that we've been discussing throughout this whole hearing, in your view, of the right of the individual to make decisions with information from a Federal agency versus the view that when something is unhealthy, there should be an effort to actually change behavior toward a healthier state.

That's not a decision for FDA to make. We operate within the law. We're more like a referee where the laws are written by you-all. I personally think the FDA is very impartial, and I don't agree with your assessment of the electronic nicotine device. No one anticipated we'd have 27 million applications to deal with. And so, there were—when I came back in, we did, just like we have talked about, the Human Foods Program. We did an entire assessment of the tobacco program and have reconfigured that considerably.

I think we are impartial referees, and when we're not, that's where public oversight is needed. So, I'd be glad to talk more about the details back in North Carolina.

Senator BUDD. Yes. Glad to do that. Deputy Commissioner Jones, reports show that newer plant-based proteins contain more sodium, and less essential amino acids and vitamin B12 compared to traditional animal-based meats. So, as the FDA considers front-of-package labeling reforms, what is the Agency doing to ensure that consumers are aware of key differences between plant-based and animal-based proteins?

Mr. JONES. Senator, we were talking about this a little earlier. We have guidance out there related to plant-based alternatives to dairy products. And in that guidance, we basically say we address both, what can you call it, but also the issue that you're raising, which is the nutritional equivalence issue. We encouraged manufacturers to voluntarily identify that a plant-based alternative may not be nutritionally equivalent to, in this case, dairy products.

We've gotten a fair amount of comments from a number of stakeholders that a voluntary disclosure may not give consumers what they need to know. We have some research that shows that consumers are not fully aware of the nutritional equivalence issue as it relates to plant-based alternatives versus dairy. So, we are taking that under consideration. And when we finalize this guidance, we will address that issue.

Senator BUDD. Thank you. Continuing on, in 2022, American families could not reliably access infant formula due to contaminated formula. Ongoing supply chain disruptions made it even worse. So, what role will the Human Foods Program play in monitoring supply chain risks that could affect the supply of critical foods like infant formula?

Mr. JONES. Yes, sir, we have done a number of things to reduce the likelihood that will ever happen again. We'd like that to be close to zero, the likelihood that ever happens.

Senator BUDD. Can you be specific on a few things?

Mr. JONES. Yes. So, we have created a critical foods program, a core of individuals within the organization. They're in the Office of Critical Foods, that are responsible for the regulatory oversight of infant formula. We are now getting monthly reports from manufacturers about manufacturing. And so, we are able to keep an eye on are store shelves as stocked as they need to be. And they're actually, and have been for some time, they're stocked at the levels they were pre the shortage.

We have got a group of inspectors who are dedicated to infant formula inspections. Previously, we did not have a dedicated group

of inspectors, and so now, there's a dedicated group of inspectors. Their job is to inspect infant formula manufacturers. They're inspecting infant formula manufacturers annually, even though the law only requires them to be inspected every 3 years. They're being inspected annually, and they're in very close contact with the programmatic folks in our Office of Critical Foods. So, we have done a number of things that we think really dramatically reduce the likelihood of anything like this happening in the future.

Senator BUDD. Thank you.

Dr. CALIFF. Senator Budd, if I may, I just want to make the point; supply chain in general is not fixed in this country, and it's very worrisome to somebody like me, not just infant formula. I don't think the issue we're going to see in the future with infant formula is what we saw with Abbott whose plant had gotten out of—basically, was contaminated.

What we're going to see is constituents of infant formula, because of the global supply chain issues, could come in shortage. And we don't control that at FDA, we're in dire need of supply chain fixes in the United States for all of the products that we regulate.

Senator BUDD. I agree that's outside the purview of FDA, but again, thank you for the additional time.

The CHAIR. Okay.

Senator Smith.

Senator SMITH. Thank you, Chair. Thank you, Chair Sanders, and Ranking Member. And welcome to the Committee. It's good to see you both, again. So, I want to talk a bit about food safety. One of the most important things that we do for Americans is to make sure that the food we eat is safe and won't make us sick. This is a basic function of government, right? And I think it's also something that's a bipartisan, nonpartisan issue.

But, so here's the thing. Of course, the work of making sure that the food supply is safe, that often happens at the state level by state employees who are doing the inspecting. And in Minnesota, that's the food inspectors at the Department of Agriculture who conduct over 13,000 inspections a year. So, how do we pay for that in Minnesota? Well, the FDA helps, right? Because tax dollars were sent back to Minnesota and all our states to help pay for these inspectors.

Here's the challenge. Minnesota's Commissioner of Agriculture, Tom Petersen, wrote me last month raising concerns about proposed FDA cuts to state and local food safety programs. And I've been told that this is going to be a big deal for Minnesota, and I'm sure Minnesota is not alone. So, Dr. Califf, if I hear what you're saying that if Congress doesn't provide adequate funding, then you can't do your job. And the Minnesota Department of Agriculture can't do its job and Americans health and safety can suffer.

I want to note that in a strong bipartisan showing of agreement, both the House and the Senate Appropriations bills for next year's funding fund food safety inspections so that no cuts would be necessary. And of course, those Appropriations bills haven't passed. That's a worry to many of us. And at the same time, we've got Elon Musk and the incoming Trump administration saying that they

think that they can find $2 trillion in cuts from the budget, which would probably start with non-discretionary funding like at the FDA.

Dr. Califf, could you just comment on this? Is there anything the FDA can do about this at this point? And what do you think we should be thinking about in Congress as we think about making sure that we have the money to do the food safety inspections?

Dr. CALIFF. I'm going to try to quickly rattle off five or six key points, and Mr. Jones may want to correct anything that I say. We've talked about this a little bit because we were not hiring, we're not able to fill all the inspectorate jobs. You all had allocated, I think it's $83 million a year, to us to go to the states for what you described. And we completely agree that this interaction of state inspectors and Federal inspectors is critical to the safety of our food supply.

But because we weren't filling all the inspectorate jobs, we had money left over that we thought was best used to go to the states. We're now hiring the inspectors. And in the reorganization of the Human Foods Program, one of the most important aspects of that is to make it clear to you-all exactly what the money is being spent on.

In my job as Commissioner, the medical product side is a lot easier that way because of the user fees. It's very much like running a business. The food side has been more like there's a lot of money and we try to do the best we can. Now it's organized in a way where you're able to see it. And so, if we're going to have enough of our inspectors, how much can go to the states? The solution to it would be to decide what the right amount is.

There are other elements of this. Right now, we can't exchange information with the states. And this is where we need a law to make it possible because our liability of disclosing commercial confidential information is different than the states. Fortunately, now with a single leader of the program, this allocation of money, I think, can be done more rationally. You may want to correct anything I said there.

Mr. JONES. No, I think that's well stated.

Senator SMITH. Well, let me get—I appreciate that, and I think my general point is that if we want to have safe food in this country that doesn't make people sick, then we need to make sure that we're keeping track of the inspections we need to do.

But you raise really another point that I want to touch on briefly, which is that, I mean, I think it would be a surprise to a lot of Americans that if the FDA has information through a voluntary recall about a product out there that's been contaminated, let's take for example, the applesauce contaminated with chromium and lead, that you're barred from sharing that information.

I mean, again, Minnesota Department of Agriculture tells me that they were forced to file a freedom of information request to get the information about the sources of lead poisoning when they're also responsible for trying to get these products off the shelves. So, this is something I'm sure you know. I've been working on a bill

that would get at this that would allow the FDA to share this information with states, and tribes, and other local governments.

Dr. CALIFF. Please hurry up. I would just—I also want to point out, this is not just about food inspections. And again, I'll be leaving January 20th, so I can say what I want to say.

Senator SMITH. This is your chance to speak truth to the somewhat powerful.

Dr. CALIFF. I think commercial confidential information in the U.S. is also one of the keys to the problems we have with supply chains. There is no reason on earth, that I know of, why companies should be able to hide information.

Senator SMITH. Now, who are we protecting when they are protected from——

Dr. CALIFF. I was on a National Academy of Medicine Committee right before I was nominated, as you may remember, for the second time. We had the industries in, they could not explain to us any good reason. And other industries came in and said and we're auto parts. Everybody knows exactly where the supplies are coming from. We don't have that. And every time we go to you-all to try to get a law passed, something happens, that Senator Sanders may have referred to, and somehow it doesn't get into the law.

I'm really appealing to you to make—look carefully at what's called commercial confidential, and particularly as it relates to supply chains and inspections as two areas where it would help a lot.

Senator SMITH. Thank you very much.

The CHAIR. Senator Markey.

Senator MARKEY. Thank you, Mr. Chairman, very much. And to all the Duke basketball fans here this morning, I just want to say you're welcome. We were glad to send Cooper Flagg down from New England down to Duke to get his postgraduate basketball training. But his mother started popping in Larry Bird videos at age six, just so you-all know. But you're welcome. I'm glad to send down the best college basketball player in America from New England.

Commissioner Califf and Mr. Jones, thank you for being here today because healthy, nutritious food is an essential part of making sure we can treat and prevent chronic diseases like heart disease, cancer, and diabetes. And I've been proud to work with my colleagues, including Senator Marshall, on supporting access to healthy foods as a means of treating chronic disease.

Dr. Califf, having experts and committed civil servants is essential for implementing evidence-based strategies for improving American's diet. Is that correct?

Dr. CALIFF. Yes.

Senator MARKEY. How important is it for the FDA's work on nutrition and chronic disease to receive support from the Secretary of Health and Human Services?

Dr. CALIFF. It's very important, very important.

Senator MARKEY. From my perspective, we have a potential nominee for Secretary of Health and Human Services who has

talked a lot about nutrition and chronic disease. Some would say what he says on diet and importance of healthy foods is reasonable.

However, one reasonable opinion does not qualify someone to run the United States Department upheld in human services. What should be disqualifying to run the Department of Health and Human Services that oversees every aspect of our healthcare system and whose actions will impact healthcare costs, access, and innovation is a nominee who has been proposed by President Trump, who has spread misinformation about vaccines and fluoridation of our water, questioned the well-proven conclusions that HIV causes AIDS, and falsely claimed that medication for depression is linked to mass shootings.

What should be disqualifying to run the Department of Health and Human Services is a history of spreading misinformation about public health measures like vaccines that result in a measles outbreak, for example, in the deaths of 83 people, many of whom were children and babies.

If we are serious about addressing chronic disease, if we are serious about closing gaps in healthcare access and moving toward a healthier America, the Senate should only confirm nominees to serve in the Department of Health and Human Services who are prepared, qualified, and serious about the responsibility of their roles. In my view, Robert F. Kennedy Jr. has disqualified himself to serve as Secretary of Health and Human Services. And I have serious concern about several other health-related nominees proposed by President Trump to be as well.

We can agree and find value in some opinions. We can agree that greed from any industry has no place in healthcare. We should agree upon that, and we should agree upon that in terms of nutrition and the role that plays in the health of Americans. But what we cannot do is sign off on nominees who would be a danger to the public health.

That is what my concern is as we move into the new year. And the nomination of Robert F. Kennedy Jr. raises all of those questions, which the next Congress is going to have to deal with. So, with that, Mr. Chairman, I yield back.

The CHAIR. Thank you very much. Let me kind of summarize my sense where we are. No. 1, I'm not quite sure that the urgency of the issue has been made as apparent as it should be, but we are dealing with an extraordinary crisis. When 1 out of 5 of our kids is obese, when millions of people are struggling with diabetes, when we spend—according to the American Diabetes Association—over $400 billion a year treating diabetes and other related illnesses, we have a major crisis.

Dr. Califf mentioned a few moments ago, and I hope you correct me if I'm misstating the essence of what you said. You said in so many words that the food industry is designing products, designing food that is unhealthy and addictive. You suggested that these foods impact the brain the way that opioids do. Is that a fair paraphrasing of what you said?

Dr. CALIFF. I would say it a bit differently. The general concepts are in play. The word addiction is a very technical word.

The CHAIR. You used the word addiction, did you not?

Dr. CALIFF. I used it with several other words around it. That said, it was just my opinion, not the view of the FDA as a policy because there's a lot of work that needs to be done to nail that down.

The CHAIR. All right. But we have had witnesses here who have said exactly that in a previous hearing. So, there is serious opinion——

Dr. CALIFF. There's no doubt that when you eat this ultra-processed food, you want to eat more of it. Whether that's addiction or not is a matter——

The CHAIR. Sounds to me like it's an addiction. And that's something that is intentionally being done by an industry which spends huge amounts of money, as you've indicated, advertising those products to children. Correct?

Dr. CALIFF. Advertising is powerful. I've had personal experience with it.

The CHAIR. All right. So, the issue is not complicated. You have an industry that makes huge profits by making our children sick and causing taxpayers to spend huge amounts of money. The question is whether or not the U.S. Congress will have the courage to take on the lobbyists who surround Capitol Hill representing the interest of the food industry, whether they'll have the courage to stand up to the campaign contributions from the industry that come flooding into our campaigns.

But I would hope that for the sake of our Country, and the point that you made, very important point, our life expectancy in the richest country on Earth is lower than every other major industrialized country. Is that correct? And the point you made about some states, I would put it in a different way, in that is working class people have life expectancies between 5 and 10 years shorter than upper income people. Is that true?

Dr. CALIFF. Yes. Education and wealth are two of the biggest factors——

The CHAIR. That's right.

Dr. CALIFF [continuing]. In these differences.

The CHAIR. This is an issue that we have got to get a handle on, and it will require courage to stand up to some very powerful special interests. I hope that Congress is prepared to do that.

That is the end of our hearing today, and I want to thank all of our witnesses for their participation. For any Senators who wish to ask additional questions, questions for the record will be due in 10 business days, December 19th by 5 p.m. I ask unanimous consent to enter Senator Casey's remarks into the record.

[The following information can be found on page 37 in Additional Material:]

The CHAIR. The Committee stands adjourned.

ADDITIONAL MATERIAL

SENATOR ROBERT P. CASEY, JR.

Thank you Dr. Califf and Deputy Commissioner Jones for being here today to discuss an issue of critical importance to the health of our Nation. This will be my last opportunity to speak at a HELP Committee hearing. I would like to take some time to look back at some of the success that we've achieved when we worked together and to implore Members of this Committee next year to work toward a future where no family needs to worry about how they will afford tomorrow's meal for their children.

We have talked a lot about encouraging healthy choices, but maintaining a healthy diet is of equal importance to ensuring that children and families have access to healthy and high-quality foods. Access to food has been the focus of much of my work on child nutrition, including through my work on the Nation School Lunch Program and the Child and Adult Care Food Program. I have long fought to expand eligibility and increase reimbursements for these critical programs.

Having sidelined the reauthorization of child nutrition programs for several years now, Congress leaves on the table immense opportunity to ensure better access to healthy foods for children and families. But access to food and helping Americans choose healthier diets cannot be mutually exclusive goals, and I encourage my colleagues on both sides of the dais to work toward a shared goal of access to healthy foods.

I also want to highlight an ongoing area where I know our witnesses remain engaged, which is the safety and security of the infant formula supply chain. The shortages in 2022, precipitated by several infant deaths linked to a contamination in a formula plant, highlighted how vulnerable this critical source of nutrition is.

While we have come a long way since 2022, the supply chain remains extremely susceptible to disruptions, and there is not a sufficient sense of urgency around the need to diversify the number of manufacturers and manufacturing sites and support smaller, newer entrants to the market. And as we work to ensure a stable supply chain, we must make every effort to ensure that the infant formulas being sold in the United States meet the regulatory standards that ensure their safety and nutritional requirements, to protect our youngest and most vulnerable infants.

I have served on the HELP Committee since 2009, and remain grateful for the good work we have done to expand access to health care, promote innovation in biomedical research and the development of new therapies to treat different causes of disease, increase access to child care, and stand up for American workers.

[Whereupon, at 11:43 a.m., the hearing was adjourned.]

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